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10/616,788	07/10/2003	Shuqian Jing	01017/39525	8243

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MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,788	JING, SHUQIAN	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's preliminary amendment filed on 10 July 2003 is acknowledged and entered. Following the amendment, the original claims 1-71 are canceled, and the new claims 72-83 are added.

Currently, claims 72-83 are pending and under consideration.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 9/8/04 is acknowledged and has been considered. A signed copy is attached hereto.

Priority

The instant application claims priority to the US applications 09/809,567 filed on 3/15/01, and 09/724,460 filed on 11/28/00, and US provisional application 60/189,816 filed on 3/16/00. For the following reasons, the Examiner finds that the present claims 72-83 are not supported in the manner required by 35 U.S.C. 112, first paragraph by the above mentioned prior applications, thus they are not entitled to the benefit of any of the filling date of the prior applications.

US provisional application 60/189,816 filed on 3/16/00 does not disclose the sequences of the present SEQ ID NO:1 and 2. The US applications 09/809,567 and 09/724,460 merely disclose the sequences of the present SEQ ID NO:1 and 2, and indicate that the polypeptide of SEQ ID NO:2 is a IL-17 receptor like polypeptide based on sequence homology. They fail to provide any specific and substantial utility directly related to SEQ ID NO:1 or 2, nor sufficient guidance or working examples to teach how to used the claimed invention. Therefore, the Examiner is not able to establish that the priority documents listed above satisfy the requirement of 35 U.S.C. 112, first paragraph. As such, the claims of the instant application are not entitled to the benefit of the filling date of any prior application.

Drawings

The drawings/figures are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 C.F.R. §1.58(a) and §1.83. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R.§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any Figures which consist only of nucleic acid or protein sequences (except those showing alignment) which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

Further, Figure 2 shows an alignment of two amino acid sequences, however, one SEQ ID NO: is missing (for hIL-17RL polypeptide). Also, the sequence indicated as "hIL-17RL" is not present in the sequence listing, and it is not SEQ ID NO:19 either, as indicated in the amendment to the specification filed on 10 July 2003 (page 2). SEQ ID NO:19 in the sequence listing has 296 amino acids, whereas "hIL-17RL" in Figure 2 has 740 amino acids. Furthermore, there is no indicated "SEQ ID NO:20" (Figure 2) in the sequence listing.

Furthermore, Figure 4 shows an alignment of SEQ ID NO:2 and 3, however, the SEQ ID NO:2 is different from the SEQ ID NO:2 in the sequence listing where the SEQ ID NO:2 has 738 amino acids, whereas the "SEQ ID NO:2" in Figure 4 has 740 amino acids.

Appropriate correction is required.

Specification

The specification is objected to for the following informalities, appropriate correction is required for each item:

According to the amendment to the specification filed on 10 July 2003 (page 2), Figure 2 depicts an overlap of SEQ ID NO:19 and SEQ ID NO:20, however, there is no SEQ ID NO:20 in the sequence listing.

Claims

Claims 73, 74 and 78 and the dependent claims 75-83 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

With respect to claims 73 and 74, they depend from claim 72, which is directed to a nucleic acid with a specifically defined sequence ((a)-(c)). However, the dependent claims 73 and 74 are directed to % (90%) and hybridization variants (of the nucleic acid of claim 72), respectively, which encompass nucleic acids not included in the dependent claim 72 (as the scope of claims 73 and 74 is broader). Thus, claims 73 and 74 can be infringed by a nucleic acid, which does not infringe claim 72. Applicants attention is directed to the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim, and a proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim. Based on such, the present claims are improperly dependent, and should be rewritten in independent form.

With respect to claim 78, it depends from claim 77, which is directed to a eukaryotic host cell, and cannot be further limited by a prokaryotic host cell of claim 78.

Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 76 is rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. The term "host cell" reads on isolated host cells, as well as host cells in the context of a multicellular, transgenic organism and host cells intended for gene therapy. The specification teaches that the nucleic acid encoding the IL-17 receptor like (IL-17RL) polypeptide can be used for gene therapy and cell therapy (page 9, lines 20-21, and page 116, the second and the third paragraphs), indicating said cell becoming integrated into the

human being and therefore being an inseparable part of the human itself. The scope of the claim, therefore, encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation "isolated" or "non-human" would be remedial. See 1077 O.G. 24, April 21, 1987.

Claims 72-83 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 72-83 are directed to an isolated nucleic acid having the nucleotide sequence of SEQ ID NO:1 or encoding the polypeptide of SEQ ID NO:2, a variant thereof, a vector comprising said nucleic acid, a host cell thereof, a process of recombinant production of the encoded polypeptide, and a composition comprising said nucleic acid. The polypeptide is a putative IL-17 receptor like (IL-17RL) polypeptide.

The specification discloses a nucleic acid, which has the nucleotide sequence of SEQ ID NO:1, and encodes a human polypeptide having an amino acid sequence of SEQ ID NO:2. Based on its sequence homology to the known human IL-17R (about 26%, see Figure 4), the specification indicates that the polypeptide of SEQ ID NO:2 is a IL-17 receptor like polypeptide, and asserts that the IL-17RL nucleic acid can be used for diagnostic and therapeutic uses in diseases and conditions such as those listed at pages 82-85 (apparently those associated with the known IL-17). However, the specification does not disclose any information about the functional property or biological significance directly associated with the IL-17RL nucleic acid or polypeptide, nor the ligand of the IL-17RL. Further, it is unclear whether the IL-17RL would even bind to IL-17 as the known IL-17R does.

Thus, the asserted diagnostic and therapeutic uses based on sequence homology to a known molecule are not considered substantial as generally the art acknowledges that the function of a protein cannot be predicted based solely on structural similarity to a known protein. For example, in the transforming growth factor (TGF) family, Vukicevic et al. (1996, PNAS USA 93:9021-9026) discloses that OP-1, a member of the TGF-β family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF-β family members BMP-2 and TGF- 1 had no effect on metanephrogenesis under identical conditions (page 9023, paragraph

bridging columns 1-2). As another example, IL-18 receptor (IL-18R) was thought to be another IL-1 receptor (IL-1R) base on the sequence homology, and therefore, designated IL-1 receptor-related protein (IL-1Rrp) when it was first discovered, and its ligand was unknown (Parnet et al., J. Biol. Chem., 1996, 271(8): 3967-70). The IL-1Rrp is now known as IL-18 receptor, has distinct ligand, and possesses distinct functional properties from that of IL-1R even though it is a member of IL-1R family. Therefore, in the instant case, the established utility for IL-17R cannot be automatically applied to the IL-17RL in the absence of any supporting evidence.

Clearly, further research and experimentation is required to identify or confirm the diagnostic and therapeutic uses of the IL-17RL nucleic acid, such as its association to specific diseases or conditions, which can then be so diagnosed or treated using said nucleic acid. There is no immediately apparent or "real world" utility for the IL-17RL nucleic acid of SEQ ID NO:1 or the encoded polypeptide of SEQ ID NO:2. However, it is a matter of law that the claimed invention must be useful in its currently available form. According to MPEP, a utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not considered a substantial utility.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. ... a patent is not a hunting license. ... [i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a nucleic acid encoding a polypeptide of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support the assertion that the IL-17RL nucleic acid/polypeptide were, as of the filing date, useful for diagnosis and treatment of any disorder, as stated at pages 82-85 of the specification, for example. Therefore, there was no "real world" use for the claimed nucleic acid

as of the filing date. Upon further research, a specific, and substantial utility might be found for the claimed isolated nucleic acid or the polypeptide encoded thereby. This further characterization, however, is part of the act of invention, and until it has been undertaken, the claimed invention is incomplete.

Additional utilities asserted for the claimed nucleic acid are noted in the specification, such as polypeptide production (page 57); producing transgenic animals (page 65); used in DNA microarray (page 66); gene therapy (page 108, the third paragraph, for example), chromosome mapping, and as a probe (page 121, lines 11-23). However, such are not considered to be specific and substantial in the absence of a specific use for the claimed nucleic acid or the polypeptide encoded thereby because these uses could be asserted for *any* cDNA.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72-83 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Further, *even if* the specification taught how to use the claimed nucleic acid or the polypeptide encoded thereby, enablement would not be commensurate in scope with claims 73 and 74 (and their dependent claims 75-83), which encompass % variants to SEQ ID NO:1, or % variants to a nucleic acid encoding a polypeptide of SEQ ID NO:2 (claim 73, for example), and hybridization variants thereof under stringent conditions (claim 74, for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 73 and 74 are directed to % variants, and hybridization variants of the nucleic acid to SEQ ID NO:1, or to a nucleic acid encoding a polypeptide of SEQ ID NO:2, which read on any or all variants meeting the nucleic acid sequence limitation, and encoding a polypeptide

either with or without any functional activity, or a possibly unrelated polypeptide (for example, a polypeptide encoded by a variant of a nucleotide sequence complementary to that encoding SEQ ID NO:2). The claims encompass an unreasonable number of nucleic acids encoding inoperative polypeptides or distinct polypeptides with functional properties unrelated to SEQ ID NO:2 (because of mere use of the arbitrary name "an IL-17R like protein" without structural limitation). However, the specification provides no guidance or working examples as to how the skilled artisan could use a nucleic acid encoding an inactive polypeptide variant of SEQ ID NO:2, as no functional limitation is associated with the variants in the claims, or a nucleic acid encoding a polypeptide with distinct function from that of SEQ ID NO:2.

Further, more with respect to the hybridization variants of said nucleotides in claim 74, it reads on any or all nucleotides hybridizing to SEQ ID NO:1 or to those encoding SEQ ID NO:2. It is well known in the art that hybridization will occur even under stringent conditions if there is only local identity between two molecules whose sequences might be totally divergent outside of that region. Such hybridized molecules may encode proteins share a common functional property with SEQ ID NO:2, yet have other distinct biological functions from those of SEQ ID NO:2. The specification does not define a specific hybridization condition for obtaining the claimed species, or working examples of any such variants, which would be within the limitations of the claims. Therefore, it would require undue experimentation in order to make and use the claimed invention in its full scope.

Furthermore, *even if* the specification taught how to use the claimed nucleic acid or the polypeptide encoded thereby, claims 81 and 82 would be further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 81 and 82 are directed to a composition comprising said nucleic acid and a pharmaceutically acceptable formulation agent, which reads on a pharmaceutical composition for gene therapy. However, the specification does not disclose a nexus between any specific disease state and a change in amount or form of said IL-17RL, nor teach any specific method or working example that would ensure one skilled in the art knowing how to practice gene therapy with the composition without undue experimentation, given the fact that the success of gene therapy is

extremely unpredictable. The disclosure in the specification would be merely an invitation to the artisan to use the current invention as a starting point for further experimentation, and undue experimentation would be required prior to use the claimed invention in gene therapy.

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen the same for activity (*if* the specification had disclosed a functional property for the IL-17RL polypeptide), and to determine how to use the inoperative polypeptides, the lack of direction/ guidance presented in the specification regarding same, the absence of working examples directed to same, the complex and unpredictable nature of the invention, and the breadth of the claims which embrace a broad class of structurally diverse variants without functional limitation, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope, *even if* the specification had taught how to use the IL-17RL polypeptide of SEQ ID NO:2.

Claims 73-83 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims 73, 74 and 80 are drawn to a nucleic acid encoding "an IL-17 receptor like protein", and having at least 90% sequence identity with a particularly disclosed sequence, SEQ ID NO:1 or a nucleic acid encoding a polypeptide of SEQ ID NO:2 (claim 73), or hybridization variants thereof under stringent conditions (claim 74), or a process of producing an IL-17RL polypeptide using a nucleic acid comprising promoter DNA other than the promoter DNA for the *native* IL-17RL (claim 80). The claims do not require that the encoded polypeptides have any specific sequence or possess any particular biological activity, nor any particular conserved structure or other disclosed distinguishing feature. Note, a definition for "an IL-17 receptor like *polypeptide*" is noted on page 11 of the specification, which refers to a polypeptide comprising, among others, "IL-17RL polypeptide variants" and "IL-17RL polypeptide derivatives". Such a definition is meaningless (assuming it also defines "an IL-17 receptor like *protein*") as it reads on any or every thing as no structure limitation is given. Thus, the claims are drawn to a genus of nucleic acids that are defined only by partial nucleic acid sequence identity.

The specification discloses *one* nucleic acid sequence with particularity, SEQ ID NO:1, and the encoded polypeptide of SEQ ID NO:2. No IL-17RL variants or "native" IL-17RL promoters of any kind meeting the limitations of these claims were ever identified or particularly described.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial nucleic acid structure in the form of a recitation of percent identity. There is not even structural identification of the polypeptide from which variants are derived, or identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, with the exception of SEQ ID NO:1 and 2, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acids and the recited "promoter DNA for the native IL-17 receptor like polypeptide", and therefore conception is not achieved, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acids encoding the amino acid sequence set forth in SEQ ID NO:2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. This is particularly important in absence of a specific known activity. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 is indefinite for the recitation "the polynucleotide encodes a polypeptide that is *an IL-17 receptor like protein*". Neither the specification nor the claim clearly defines the term (structure). Without specifically defined sequence structure and/or function, the term "an IL-17 receptor like protein" is meaningless as it is merely an arbitrary name, and the metes and bounds of the structure of such a protein are not clear. For example, is a polypeptide encoded by a variant 90% identical to a nucleotide sequence complementary to that encoding SEQ ID NO:2 "an IL-17 receptor like protein"? As the claimed polynucleotide is a random variant (with 90% identity) of a particular nucleic acid sequence, and encodes a protein with no defined structure or function, the metes and bounds of the claimed polynucleotide, therefore, cannot be determined.

Claim 74 is similarly indefinite for the recitation "an IL-17 receptor like protein" as it is unclear what it is meant. Claim 74 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: hybridization steps. The claim recites "the nucleic acid molecule hybridizes ... under the following stringent conditions" in lines 2-3, however only washing condition is provided.

Claim 75 recites the limitation "*the nucleic acid molecule* of any one of claims 72, 73 or 74". There is insufficient antecedent basis for this limitation in the claim with respect to claim 73, as claim 73 recites "an isolated *polynucleotide*". It is noted that the term "the nucleic acid molecule" is recited in claim 73 (line 2), however, it is for the nucleic acid molecule of *claim 72*, not claim 73. Claims 81 and 83 are similarly indefinite.

Claim 79 is indefinite for failing to adequately point out what applicants see as the invention because of the following: the claim recites "producing *an IL-17 receptor like polypeptide*", which does not require the production of the specific polypeptide encoded by said recombinant or isolated nucleic acid contained in said vector, as the host cell of claim 76 may also produce polypeptides other than the polypeptide encoded by the transformed or transfected expression vector. It is also noted that the polynucleotide of claim 73, and the nucleic acid of claim 74 encode "an IL-17 receptor like *protein*" (instead "an IL-17 receptor like *polypeptide*"), therefore, it is not even clear whether the two terms refer to the same molecule. Further, although the specification defines the term "an IL-17 receptor like polypeptide" (page 11), said definition does not specifically define the structure of the molecule. Therefore, the term "an IL-17 receptor like polypeptide" is merely an arbitrary name without defined structure or function. As such, it is unclear what "an IL-17 receptor like polypeptide" is (for example, is a polypeptide encoded by a nucleotide sequence complementary to SEQ ID NO:1 or a variant thereof "an IL-17 receptor like polypeptide"?); what "suitable conditions" is meant; and what polypeptide must be produced by said process. The metes and bounds of the claim, therefore, cannot be determined.

Claim 80 recites the limitation "*the native* IL-17 receptor like polypeptide" in line 2. There is insufficient antecedent basis for this limitation in the claim, and also it is unclear as to what the term refers. The claim is further indefinite for the recitation "the promoter DNA for IL-17 receptor like *polypeptide*" as the promoter is a part of the nucleic acid, not the polypeptide.

Claims 81 and 83 are further indefinite for the recitation "*a* nucleic acid molecule of any one of claims 72, 73 or 74" because it is unclear whether the term "a nucleic acid molecule" represents a partial or the whole sequence of those recited in claims 72, 73 or 74. Replacing "an" with "the" would be remedial.

The remaining claims are included in this rejection because they are dependent from specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

Rejections Over Prior Art:

It is determined that the effective filing date for the instantly claimed invention is 7/10/03 (see "Priority" above), which is the actual filing date of the present application. However, the filing date of the earlier application 09/724,460, 11/28/00, has been used for the purposes of applying the prior art below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 73-83 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorman, US 2003/0092881 A1.

Gorman discloses a nucleic acid, SEQ ID NO:9, which nucleotides 70-2280 comprise the encoding sequence for the present SEQ ID NO:2 with 97.8% sequence similarity to that encoding SEQ ID NO:2 (see appended computer printout of sequence search results). Gorman's nucleic acid of SEQ ID NO:9 encodes a human cytokine receptor DCRS8 having an amino acid sequence of SEQ ID NO:10, which is 97.8% identical to the present SEQ ID NO:2 (see appended computer printout of sequence search results, and page 15, Table 3. Note, "SEQ ID NO:13 and 14" in Table 3 are mis-cited as they are not the same as SEQ ID NO:13 and 14 in the sequence listing, instead, "SEQ ID NO:13 and 14" of Table 3 equal to SEQ ID NO:9 and 10 of the sequence listing). Thus, Gorman's nucleic acid of SEQ ID NO:9 anticipates the present claims 73 and 74 as being a polynucleotide comprising a nucleic acid sequence at least 90% identical to a nucleotide sequence encoding the polypeptide of SEQ ID NO:2 (as claim 73); or a nucleic acid molecule hybridizing to the complement of SEQ ID NO:1 (claim 74). Note, with respect the limitation "encodes a polypeptide that is an IL-17 receptor like protein" in the claims, Gorman's nucleic acid meets such a limitation because it meets the sequence limitation of the claims, and encodes a human cytokine receptor, and because the claims defines neither the

structure nor the function of the encoded polypeptide. Additionally, Gorman teaches expression vectors containing said receptor gene, operably linked to suitable genetic control elements that are recognized in a suitable host cell, such as a prokaryotic or eukaryotic promoter system (page 38, [0123]), wherein the vectors comprise, among others, viruses (page 38, [0125]). Further, Gorman teaches that the suitable host cells include prokaryotes and eukaryotes (page 38, [0128]). As such, the reference also anticipates claims 75-78 and 83. Furthermore, Gorman teaches a process of producing said polypeptide by culturing transformed cells (with said vectors) in a nutrient medium, thus permitting the protein to accumulate, and recovering the protein either from the culture or the culture medium (page 38, [0126]). Therefore, the reference anticipates claims 79 and 80. Furthermore, Gorman teaches a nucleic acid composition including the nucleic acid encoding the DCR8 polypeptide, or an expression vector thereof (page 2, [0015]). Although Gorman does not explicitly mention "a pharmaceutically acceptable formulation agent" in said composition, given the fact that the expression vector is used for transformation/ transfection, which requires liquid nucleic acid composition, Gorman's nucleic acid composition anticipates the present claims 81 and 82 because liquid such as water, buffer and medium, for example, are all considered "pharmaceutically acceptable" formulation agent/carrier (page 44, the first paragraph of the left column).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
4/8/06